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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,914	03/07/2006	Alfred Marchal	09997.0127USWO	9556
23552	7590	10/10/2006	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			CHO, JENNIFER Y	
			ART UNIT	PAPER NUMBER
			1621	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/542,914	MARCHAL, ALFRED	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer Y. Cho	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 3 & 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |  |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/20/05</u> | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

Receipt is acknowledged of the Information Disclosure Statement filed 7/20/05. Also received was the combined Declaration and Power of Attorney filed 3/7/06.

### **Claim Objections**

Claims 3 and 11 are objected to because of the following informalities:

Shambourg's disease is misspelled. The correct spelling is Schamberg's disease.

Appropriate correction is required.

### **Claim Rejections – 35 USC 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The process must be defined by the presentation of at least one process step. A use claim is non-statutory since it does not present a positive step recitation. See MPEP 2173.05(q).

### **Claim Rejections – 35 USC 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 provides for the use of a composition comprising an adequate pharmaceutical or cosmetic carrier (or diluent) and a sufficient amount of a Vitamin K1 oxide but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

### **Claim Rejections – 35 USC 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1621

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elson (WO 97/39746) in view of Elson (U.S. Patent 5,510,391), further in view of Crandall (U.S. Patent 5,945,409).

Elson (WO) teaches a process for the treatment of skin conditions by the application of a Vitamin K1 cream using ethyl alcohol and lecithin granules for cosmetic or pharmaceutical formulation. (see page 6, lines 11-23) Ethyl alcohol, also known as ethanol, is recognized as a solvent and as a penetration enhancer. The lecithin granules are derived from phospholipids. Creams are well known cosmetic carriers as shown in Elson (WO). (see page 6, lines 1-5)

Elson (WO) is deficient only in the sense that it does not teach the use of the applicant's penetration enhancer ethoxy diglycol, nor does it teach the particular Vitamin K1 derivative, Vitamin K1 oxide. However, the reference teaches a generic Vitamin K1 and discloses ethanol, a well-known penetration enhancer. (see page 6, line 17)

Elson ('391) teaches the equivalency of Vitamin K1 analogs in a cosmetic and/or pharmaceutical formulation for use in treating the skin. (see column 7, lines 18-20) Vitamin K1 oxide would be considered to be a species of the generic teaching of Elson ('391). Additionally Elson ('391) teaches the presence of ethyl alcohol. (see column 3, line 47)

Crandall teaches the equivalency of penetration enhancers, including ethoxy diglycol and ethyl alcohol. (see column 5, line 55). Also, Crandall teaches the equivalency of any liquid, gel, salve, solvent, diluent and fluid ointment base as an effective carrier. (see column 5, lines 35-37) In addition, Crandall discloses the option to have additional vitamins present. (see column 14, lines 38-40)

Regarding claims 4, 5, 8, 14, 15 and 17 which presents limitations as to the particle size of the phospholipids and the percentage of the compound of Formula 1, it is the position of the examiner that one of ordinary skill in the art, at the time of the invention, would through routine and normal experimentation determine the optimization of these limitations to provide the best effective variable depending on the results desired. Note that the prior art provides the same effect desired by applicant, the treatment of the same skin conditions.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to use any penetration enhancer for the ethyl alcohol of Elson (WO) or those recited in Elson ('391), since the enhancers are recognized as being equivalent within the cosmetics technology. (see Crandall, column 5, line 55).

The expected result would be the effective delivery of the cosmetic formulation to the skin to treat the various conditions of the skin, e.g. vascular disorders, spider veins and blotches.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Y. Cho whose telephone number is (571) 272 6246. The examiner can normally be reached on 8 AM - 5 PM.

Art Unit: 1621

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272 0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JC JC

THURMAN K. PAGE  
SUPERVISOR, PATENT EXAMINER  
TECHNICAL CENTER 1600